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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,236	09/17/2003	John H. Stevens	15302ZYXWAZ (HRT-176)	6287
7590 08/24/2005 Scully, Scott, Murpgt & Presser 400 Garden City Plaza Ste. 300 Garden City, NY 11530			EXAMINER ISABELLA, DAVID J	
			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/665,236

Applicant(s)

STEVENS ET AL.

Examiner

DAVID J. ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5 and 10-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5 and 10-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Withdrawal of Final

Upon further consideration of the claims, the examiner has withdrawn the finality of the last office action and has applied new art directed to tools for gauging dimension of anatomical features including volume and size.

Status of the Claims

Currently, claims 2-5,10-21 are pending for action.

Status of the Terminal Disclaimer

The Terminal disclaimer as filed on 11/20/2004 has not been approved for entry.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-5,10-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derek Gordon 1997 (Publication Time Publication; "Too Big a Heart") in view of Berman et al (5613302) and/or either of Kress (4624671) or Hinnenkamp et al (5814098).

The method of reshaping a patient's heart comprising reducing the dimension of the left ventricle by a predetermined amount is fully disclosed by Batista, et al. While

Batista fails to specifically set forth the steps of gauging the size of the left ventricle and determining the amount by which the left ventricle should be reduced from the gauging, such steps are inherent and essential to performing the reshaping of the ventricle chamber. Whether the gauging is in the form of a mental, visual, imaging or physical step, it is clear that Batista, et al fulfilled the steps as claimed by applicant in the reduction of the size of the patient's left ventricle.

Dr. Batista and the Batista procedure was developed in the early 1980s. The procedure involved a partial left ventriculectomy in which an enlarged heart muscle wall is removed and the ratio heart diameter to mass could be returned to a near normal level. The determination of muscle mass to heart size was found to be based on the law of La Place: $mass = 4 \times radius^3$. This relationship as described by Batista, inherently requires the step of gauging the size of the left ventricle so that determination of the amount of tissue that should be removed which will allow the heart to return to near normal level. Moreover, the article states that this procedure was performed on a Brazilian patient back in 1994. Clearly, the procedure for reshaping a patient's heart comprising: gauging the size of the left ventricle; determining the amount by which the left ventricle should be reduced from the gauging of its size; and reducing the dimension of the left ventricle in accordance with the determined amount is fully met by what is widely known as the "Batista procedure". The size of the heart according to Batista is proportional to the circumference (ie determined radius of the heart). These dimensions may be obtained by well known circumferential measurements or volumetric determinations known in any art for determining dimensional parameters of a three

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dimensional structure including body organs. Each of Kress, Hinnenkamps, et al and Berman et al teach methods for determining size of three dimensional tissues. While the prior art is not specific to the organ of the heart, applicant's claims is not specific to any particular features of the tool used to obtain the measurements used in determining the dimension of the ventricle. Applicant's method steps broadly defines the gauging steps as using an adjustable band or a expansible member. The art clearly establishes that the broad concepts for gauging dimensional characteristics of a three dimensional object with the use of a band length and/or an expansible member is well known in any art. Lacking any specific features of the tools to accomplish the measurements, examiner contends to use either types of measuring devices, tape or expansion type, to determine the physical size of the affected heart tissue would have been obvious to one with ordinary skill in the art at the time of the invention thereof.

Claims 4, 5, 10-12 see expansion member of Kress and Hinnenkamps et al.

Claims 13-16, 18-21, see reduction method as taught by Bastita.

Claim 17, see band of Berman et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-5,10-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6125852. Although the conflicting claims are not identical, they are not patentably distinct from each other because the broad steps of reshaping the patient's heart by gauging the size of the left ventricle, determining the amount of tissue that should be reduced from the gauging and reducing the dimension of the left ventricle in accordance with the determined amount is fully set forth in the claims of US Patent 6125852. Claim 5 of US Patent 612852 discloses the steps of sizing the ventricle with an instrument. The specification sets forth two instruments for sizing the ventricle, the band and the inflatable volume device.

No payment under 37 CFR 120 (d) accompanied the response filed on 11/2/2004.

Conclusion

Applicant's arguments filed 11/02/2004 have been fully considered but they are not persuasive. Applicant's error in providing the correct publication date directed to the Batista Publication resulted in the examiner need for withdrawing the outstanding

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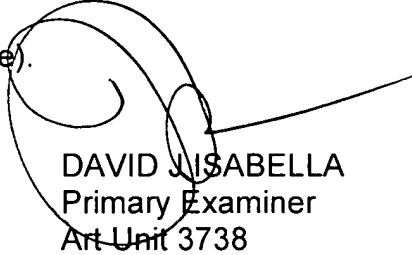
rejection. At best, the date of applicant's invention to the reshaping of the heart dates including gauging the size of the left ventricle would not receive coverage back to the earlier filed application 08/685262. There is no support in the earlier application for the steps of "gauging the size of the left ventricle". There is, however, support for assessing the approximate volume of the left ventricle.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

DJI
JUNE 16, 2004